



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/759,280

01/20/2004

Joanne Peart

02940086CA

6861

30743

7590

05/19/2010

WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

05/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOANNE PEART, PETER R. BYRON, ARON H. LICHTMAN,
and BILLY R. MARTIN

Appeal 2009-013613
Application 10/759,280
Technology Center 1600

Decided: May 19, 2010

Before TONI R. SCHEINER, DONALD E. ADAMS, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 43, 46-48, 50, 52-55, and 57-63 (App. Br. 5). We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to an aerosol-dispensable pharmaceutical composition (claims 43, 46-48, 50, 53-55, 57, and 58); an aerosolized pharmaceutical composition (claims 59 and 60); a method of aerosolizing a tetrahydrocannabinol (claims 61 and 62); and a non-CFC aerosolized dispensable pharmaceutical composition comprising tetrahydrocannabinol (claim 63). Claims 57 and 59 are illustrative:

57. An aerosol-dispensable pharmaceutical composition comprising: tetrahydrocannabinol and hydrofluoroalkane, wherein the composition is aerosol-dispensable.

59. An aerosolized pharmaceutical composition comprising: respirable droplets comprising a tetrahydrocannabinol.

The rejections presented by the Examiner follow:

1. Claims 43, 46-48, 50, 53-55, and 57-63 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Mechoulam¹ or Volicer² in view of McNally.³
2. Claim 52 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Mechoulam or Volicer in view of McNally and Pars.⁴
3. Claims 43-48, 50, 52-55, and 57-63 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Pars and McNally.

¹ Mechoulam et al., US 5,635,530, issued June 3, 1997.

² Volicer, US 5,804,592, issued September 8, 1998.

³ McNally et al., US 5,653,961, issued August 5, 1997.

⁴ Pars et al., US 3,728,360, issued April 17, 1973.

4. Claims 43, 46, 48, 50, 52-55, and 57-63 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of Peart I.⁵

5. Claims 43, 46, 48, 50, 52-55, and 57-63 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of Peart II.⁶

We reverse the rejections under 35 U.S.C. § 103(a). We affirm the rejections under the judicially created doctrine of obviousness-type double patenting. We enter a new ground of rejection of claim 59 under 35 U.S.C. § 103(a).

OBVIOUSNESS:

ISSUE

Does the evidence relied upon by the Examiner support a prima facie case of obviousness?

FINDINGS OF FACT

FF 1. The Examiner relies on Volicer and Mechoulam to teach that tetrahydrocannabinol (THC) compositions can be formulated as an aerosol (Ans. 5-6).

FF 2. Volicer's only disclosure of an aerosol formulation of a tetrahydrocannabinol is that dronabinol, a delta-9-tetrahydrocannabinol (Δ^9 -THC), "alone or in combination with other suitable components, can be made into aerosol formulations to be administered via inhalation. These

⁵ Peart et al. (Peart I), US 6,509,005 B1, issued January 21, 2003.

⁶ Peart, et al. (Peart II), US 6,713,048 B2, issued March 30, 2004.

aerosol formulations can be placed into pressurized acceptable propellants, such as dichlorodifluoromethane, propane, nitrogen, and the like” (Volicer, col. 5, ll. 3-7).

FF 3. Mechoulam’s only disclosure of an aerosol formulation of THC, specifically tetrahydrocannabinol-7-oic acids and derivatives thereof, “may be formed as aerosol, for intra-nasal and like administration” (Mechoulam, col. 5, ll. 33-35).

FF 4. The Examiner relies on Pars to teach “pharmaceutically acceptable salts of THC ester derivatives” (Ans. 8).

FF 5. Pars contains no disclosure of an aerosol formulation of THC.

FF 6. The Examiner relies on McNally to teach that butixocort, a non-THC drug, can be solubilized in “alcohols, including ethanol” and formulated into an aerosol using a hydrofluoralkane [(HFA)] propellant (Ans. 6; *see also* Peart Declaration⁷ 5: ¶ 14).

FF 7. There is no dispute on this record that McNally does not teach an aerosol formulation comprising THC.

FF 8. Peart declares that “THC and butixocort . . . definitely are not thought of as interchangeable for purposes of an aerosol formulation” (Peart Declaration 5: ¶ 14).

FF 9. Weers declares that THC is unexpectedly soluble in HFAs (Weers Declaration⁸ 3: ¶ 6). In this regard, Weers declares that the “solubility of THC in HFA propellants is an order of magnitude higher than” butixocort, beclomethasone dipropionate and flunisolide hemihydrate, oleic acid and

⁷ Peart Declaration, executed November 6, 2007.

⁸ Weers Declaration, executed March 27, 2006.

sorbitan trioleate, which are “common bronchodilators, corticosteroids and surfactants” (Weers 2-3: ¶ 4).

PRINCIPLES OF LAW

Obviousness does not require absolute predictability; however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success can support a conclusion of non-obviousness. *In re Rinehart*, 531 F.2d 1048, 1053-54 (CCPA 1976).

ANALYSIS

The Examiner concludes that “[i]t would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Mechoulam or Volicer with McNally, because all inventors teach pharmaceutical aerosol formulations comprising propellant”; the use of “chlorofluorocarbons were being phased out in favor of alternatives”; and McNally teaches that “the use of cosolvents (e.g. ethanol) in aerosol formulations was well known” (Ans. 7).

In addition, the Examiner concludes that since butixocort and THC are both hydrophobic compounds and McNally teaches the use of ethanol to solubilize hydrophobic active agents “an ordinary skilled artisan would have had a reasonable expectation of obtaining solution aerosol formulations of THC that also comprised HFA and ethanol” (Ans. 13).

We are not persuaded.

The Examiner failed to establish a nexus between THC and butixocort. In addition, the Examiner failed to establish a nexus between HFA and the propellants suggested by Volicer, or those known in the art to

be useful in combination with THC as suggested by Mechoulam. In sum, the preponderance of evidence on this record supports the conclusion that THC and butixocort are not “interchangeable for purposes of an aerosol formulation” (FF 8). Therefore, the evidence on this record fails to establish that a person of ordinary skill in this art would have had a reasonable expectation of successfully substituting THC for the butixocort in McNally’s formulation.

In addition, the evidence of record establishes that THC was unexpectedly soluble in HFAs (FF 9). The Examiner provides no persuasive evidence on this record to suggest that a person of ordinary skill in this art, at the time the invention was made, would have reasonably expected HFA to be an effective propellant system for THC, or that THC would be more soluble in an HFA propellant than other “common bronchodilators, corticosteroids and surfactants” (*id.*).

Pars taken with McNally, alone or in combination with Mechoulam or Volicer, fails to provide the missing evidentiary basis to support the obviousness rejections of record.

CONCLUSION OF LAW

The evidence relied upon by the Examiner fails to support a prima facie case of obviousness.

The rejection of claims 43, 46-48, 50, 53-55, and 57-63 under 35 U.S.C. § 103(a) as unpatentable over the combination of Mechoulam or Volicer in view of McNally is reversed.

The rejection of claim 52 under 35 U.S.C. § 103(a) as unpatentable over the combination of Mechoulam or Volicer in view of McNally and Pars is reversed.

The rejection of claims 43-48, 50, 52-55, and 57-63 under 35 U.S.C. § 103(a) as unpatentable over the combination of Pars and McNally is reversed.

OBVIOUSNESS-TYPE DOUBLE PATENTING:

The Examiner has maintained the rejection of:

Claims 43, 46, 48, 50, 52-55, and 57-63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of Peart I; and

Claims 43, 46, 48, 50, 52-55, and 57-63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of Peart II.

Appellants have elected not to address these rejections on this appeal (*see* App. Br. 9 and 22).

Accordingly, both rejections under the judicially created doctrine of obviousness-type double patenting are summarily affirmed. Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

NEW GROUND OF REJECTION:

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection: Claim 59 is rejected under 35 U.S.C. § 102(a) as being anticipated by Volicer, as evidenced by page 9 of Appellants' Specification.

Claim 59 is drawn to an aerosolized pharmaceutical composition. The composition comprises: respirable droplets comprising a THC. Claim 59 does not require a specific propellant, formulation, efficacy, or concentration of respirable droplets.

Volicer teaches that the THC, delta-9-tetrahydrocannabinol (Δ^9 -THC), "alone or in combination with other suitable components, can be made into aerosol formulations to be administered via inhalation. These aerosol formulations can be placed into pressurized acceptable propellants, such as dichlorodifluoromethane" (FF 2).

Appellants' Specification establishes that those of ordinary skill in this art, at the time this invention was made, knew how to formulate Δ^9 -THC into moderately effective aerosol formulations comprising chlorofluorocarbons (Spec. 9: 15-20). There is no evidence on this record to support the conclusion that these formulations would not have resulted in a composition that comprises some degree of respirable droplets comprising THC.

TIME PERIOD FOR RESPONSE

Regarding the affirmed rejections, 37 C.F.R. § 41.52(a)(1) provides "Appellant may file a single request for rehearing within two months of the date of the original decision of the Board."

In addition to affirming the Examiner's rejections of one or more claims, this decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner....

(2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record....

Should the Appellant elect to prosecute further before the Examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the Appellant elects prosecution before the Examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences

Appeal 2009-013613
Application 10/759,280

for final action on the affirmed rejection, including any timely request for rehearing thereof.

AFFIRMED-IN-PART

cdc

WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON VA 20190